Memorandum

To: Judge Patti B. Saris

From: Professor Ernst R. Berndt

Re: Pharmaceutical Average Wholesale Price Litigation (M.D.L. No. 1456, Civil Action No. 01-12257-PBS) Follow-Up

Date: 9 August 2005

The assignment I was given at our meeting on Wednesday, July 27, 2005, was to look further at the controversy among experts on the possibility and/or feasibility of going from the five-digit Healthcare Common Procedure Coding System ("HCPCS") J, Q, P or S codes contained in claims data to a *unique* 11-digit NDC code containing data on specific product, strength, dosage form, formulation, and package size/number of units – a procedure known as "crosswalking". Such crosswalking will be necessary in order to track actual physician-administered drug utilization and unit prices. I was also asked to report back to you on what I learned is the nature and information content contained in claims forms when providers seek to be reimbursed for services provided to non-Medicare patients receiving physician-administered drugs or biologics. We discussed the results of my additional research in a telephone conversation on Thursday, August 4, 2005. You asked that I send you a letter or memorandum summarizing our discussion. This memorandum is my response to that request. Since that meeting I also was able to speak with several researchers whom I had not been able to contact before August 4; this memorandum also incorporates their general observations.

I began by indicating to you what I had done subsequent to our July 27 meeting. Since the private sector often employs forms and conventions adopted by the Centers for Medicaid and Medicare Services ("CMS"), I first went to the Medicare website (http://www.medicarenhic.com/providers/fees/drugallowlimits_jan05.htm) and looked up items concerning claims review and adjudication procedures, as well as current (but not historical) payment allowance limits for all Medicare Part B drugs and vaccines, including their five-digit HCPCS codes, as well as their short generic description. This constituted a complete list of J, P and Q codes, as well as five-digit numeric codes (typically beginning with a "9") for various vaccines. I also downloaded a CMS document 4460.1 – 4460.2 ("Claims Review and Adjudication Procedures").

I then examined related Medicare and non-Medicare materials at http://www.reimbursementcodes.com/, a website that sells services helping providers obtain reimbursement from CMS and private sector payors, and explicitly offers clients an NDC crosswalking service. I also looked up several other reimbursement assistance and biotech firm websites (e.g., http://www.reimbursementconnection.com/neulasta/coding_process/completing_fo... , http://www.reimbursementconnection.com/neulasta/coverage_reimbursement/medicare.jsp, http://www.reimbursementconnection.com/neulasta/coverage_reimbursement/blue_cross.jsp, http://www.fludara.com/hcp/reimburse.html, and

http://www.doxiline.com/pubs/health/payer.pdf) that provided information on health care payment systems, reimbursement procedures, and sample claims forms such as HCFA-1450/UD-92, and HCFA-1500.

In addition to researching information on these various websites, I contacted several researchers and previous collaborators who all have considerable experience in and knowledge of this general area, and who to the best of my knowledge have not been involved in this AWP litigation: Professor Jonathan Skinner, a health economist at Dartmouth; Professor Joseph Newhouse, a health economist at the Harvard Medical School (and member of the Board of Directors of Aetna); and Professor C. Daniel Mullins, Chair of the Pharmaceutical Health Services Research Department at the University of Maryland School of Pharmacy, and lead author of a July/August 2005 *Health Affairs* article, "Variability And Growth in Spending For Outpatient Specialty Pharmaceuticals". Finally, I contacted Dr. William Crown, a health economist who was at MedStat when I collaborated with him, but is now Senior Vice President, Health Economics and Outcomes, at i3magnifi, an Ingenix Company that is I believe a subsidiary of United Health Care. Dr. Crown put me in touch with a professionally accredited coding expert named Regina Magnani, who is a Registered Health Information Technician responsible for much of the HCPCS Level II product content at an organization that prepares reference manuals for providers' reimbursement personnel.

While this set of websites and individuals is clearly not exhaustive, I believe it represents a respectable and credible set of sources and references that would at least let me obtain a preliminary answer to the issues you asked me to investigate.

What I have learned from this mini-research project is the following. First, I obtained what initially appeared to be conflicting information, but may not in fact be inconsistent. Some of these websites and individuals suggested the crosswalk is very feasible and comprehensive, while others implied it is reliable for only a portion of physician-administered drugs. Another observation was that there is very substantial heterogeneity in the quality of programmers and information technology personnel among insurers, even today, and that the crosswalk might be feasible for some organizations but not for others.

There seem to me to be two general comments I can comfortably make at this point. The first is that the crosswalk is more likely to be feasible and reliable for the more recently introduced and typically more expensive biotech physician-administered drugs, and much less likely to be feasible and reliable for older, and in particular, multi-source off-patent and generic products. Second, it appears that provider and payor information technology systems that support claims adjudication and reimbursement have become increasingly capable of capturing and retaining details of transactions over time, as payors have increasingly focused on cost-monitoring and cost-containment for the physician-administered category of drugs. Thus I expect that the extent of feasible crosswalking will be greater in the last several years than, say, prior to 2000.

Finally, with respect to actual filed claims forms and their content, all I can comfortably say at this point without immersing myself into a very detailed and lengthy investigation is that there appears to be considerable diversity in how much detailed information is retained as these

claims are aggregated up and paid, although the increased intensity in use of information technology (both hardware and software) typically involves keeping ever more detailed information farther up the reimbursement process.

In summary, just how feasible and costly it will be to crosswalk reliably between the HCPCS and NDC codes will likely vary over time, across payors and among the various physician-administered drugs. Whether the crosswalking will be sufficiently reliable and comprehensive in the class certification context remains I think an open empirical issue. As a result, given what I have learned from this additional mini-research project, I do not believe I would change or add anything to what I originally submitted in my February 9, 2005 report to you. Specifically, what I wrote in ¶198 on page 106 is I believe still the case: "Just how labor intensive crosswalking will be, and how individualized the process will need to be in order to be reliable, particularly going back in time to the 1990s, is unclear to me at this point. This is an important issue that merits thoughtful and concise clarification by both Plaintiffs' and Defendants' experts."

I am available to discuss these and other matters further with you, should you deem that useful and appropriate.

Respectfully submitted,

Ernst R. Berndt, Ph.D.